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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,152	02/18/2005	Roger Alberto	1582 WO/US	5284
7590 Mallinckrodt Inc. 675 McDonnell Boulevard PO Box 5840 Hazelwood, MO 63134			EXAMINER GROSS, CHRISTOPHER M	
			ART UNIT 1639	PAPER NUMBER
			MAIL DATE 03/31/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/525,152

Applicant(s)

ALBERTO ET AL.

Examiner

CHRISTOPHER M. GROSS

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-17, 20-24, 28 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-17, 20-24, 28 and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

3DETAILED ACTION

Responsive to communications entered 9/22/2008. Claims 15-17,20-24,28,32-36 are pending. Claims 15-17,20-24,28,32-36 are examined herein.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/22/2008 has been entered.

Election/Restrictions

Applicant's argument regarding claims 35 and 36 depending on claim 22 which reads on the elected invention is deemed persuasive thus claims 35-36 are hereby rejoined.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) [taken from MPEP 201.01]

The present application, filed 2/18/2005 claims priority as a 371 of PCT/US03/27665 filed 09/02/2003 and further to European application (EPO) 02078743.8 filed 09/03/2002. Nevertheless, the L being a single bond is not disclosed in the European application or the PCT application. L is indicated, for example in claims 1 of the PCT application as being either present or absent. The examiner submits that L being absent does not necessarily constitute a single bond.

Response to Arguments

On p 9 of the remarks entered 9/22/2008, applicant does not provide any counterarguments concerning priority of the present application, therefore 2/28/2005 remains the date for the purposes of prior art concerning claims 15-17,20-24,28,32-36.

Withdrawn Rejection(s)

The rejection of claims 15,20,21,24,27 under 35 U.S.C. 102(b) as being anticipated by **Aya et al** (US Patent 3,899,472) is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 15, 20,21,24,27 and 16,17,28,32,33,34 under 35 U.S.C. 103(a) as being unpatentable over **Aya et al** (US Patent 3,899,472) in view of **Dunn-Dufault et al** (2000 Nuclear Medicine and Biology 27:803-807 – IDS entry 4/27/2007) is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 22,23 under 35 U.S.C. 103(a) as being unpatentable over **Aya et al** (US Patent 3,899,472) **in view of Dunn-Dufault et al** (2000 Nuclear Medicine and Biology 27:803-807 – IDS entry 4/27/2007) as applied to claims 15, 20,21,24,27

and 16,17,28,32,33,34 above, and further in view of **Alberto et al** (1998 JACS 120:7987-7988 - IDS entry 4/27/2007) is hereby withdrawn in view of applicant's amendments to the claims.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-17,20-24,28,32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by **Mundwiler et al** (2004 Bioconjugate Chem. 15:195-202; public availability date on the Web 12/16/2003)

The claimed subject matter per claim 15 is drawn to

A solid phase bound organic conjugate represented by formula (I)

wherein the sphere is a solid phase support;

C is a carbon atom;

R4 and R5 are independently selected from the group consisting of H, aliphatic substituents, aromatic substituents, RO, RS and (R)2N, wherein R is an aliphatic or aryl group; L is a single bond; and each of R1 and R2 is independently a metal coordinating group, a non-coordinating organic group, a metal coordinating group derivatized with a biologically active molecule, or a non-coordinating organic group derivatized with a biologically active molecule, wherein at least one of R1, and R2 is independently selected from the group consisting of [R3-picoly], R3-imidazole or an R3-amine]

wherein R3 is directly attached to the tertiary amine or is an aliphatic chain containing between 1 and 3 carbons directly attached to the tertiary amine.

Claims 16-17,20-24,28,32-36 represent variations thereof.

Mundwiler et al et al teach, throughout the document and especially the title preparation of Technetium-99m complexes via metal assisted cleavage from a solid phase.

In Scheme 1 and Chart 1, Mundwiler et al teach preparation of a Technetium tridentate ligand with a TentaGel solid support bearing a tertiary amine amino or picolylamine groups, which reads on claims 15 and 20 when L is a single bond; $R_4=R_5=H$; R_1 is R_3 picolylamine with one carbon atom or an amine with two carbon atoms.

Said TentaGel is hybrid of polyethyleneglycol and polystyrene (elected species), reading on claims 17 and 34.

Mundwiler et al teach on p 200 penultimate paragraph line 8, introduction of pharmaceutically active small molecules such as biotin (elected species), reading on claims 16,32,33 and 28.

The labeling procedure set forth in the right column of p 197 of Mundwiler et al utilizes uses a kit including solution of a solution of $[^{99m}\text{TcO}_4]^-$ for preparing $[^{99m}\text{Tc}(\text{OH}_2)_3(\text{CO})_3]^+$ and appears to have been done with a syringe fitted with a syringe filter. Said syringe is taken as the container or vessel or column set forth in claims 20 and 21. Said syringe filter is taken as the facility for filtrations set forth in claim 24. Said $[^{99m}\text{Tc}(\text{OH}_2)_3(\text{CO})_3]^+$ reads on claims 22,35 and 36. Said solution of $[^{99m}\text{TcO}_4]^-$ reads on claim 23.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER M. GROSS whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

/ Christopher S. F. Low /
Supervisory Patent Examiner, Art Unit 1639